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Dispute over drug in feed limits U.S. meat exports

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Pigs are often fed ractopamine up until slaughter to promote growth.

By Helena Bottemiller, January 25, 2012

A drug used to keep pigs lean and boost their growth is jeopardizing the nation's exports of what once was known as "the other white meat."

The drug, ractopamine hydrochloride, is fed to pigs and other animals right up until slaughter and minute traces have been found in meat. The European Union, China, Taiwan and many others have banned its use, citing concerns about its effect on human health, limiting U.S.

meat exports to key markets.

Although few Americans outside of the livestock industry have ever heard of ractopamine, the feed additive is controversial. Fed to an estimated 60 to 80 percent of pigs in the United States, it has resulted in more reports of sickened or dead pigs than any other livestock drug on the market, an investigation of Food and Drug Administration records shows.

Growing concern over sick animals in the nation's food supply sparked a California law banning the sale and slaughter of livestock unable to walk, but that law was struck down by the Supreme Court Monday. Meat producers had sued to overturn California's ban, arguing that the state could not supercede federal rules on meat production. The court agreed.

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The FDA, which regulates livestock drugs in the United States, deemed ractopamine safe 13 years ago and approved it, setting a level of acceptable residues in meat. Canada and 24 other countries approved the drug as well.

U.S. trade officials are now pressing more countries to accept meat from animals raised on ractopamine — a move opposed by China and the EU. Resolving the impasse is a top agricultural trade priority for the Obama administration, which is trying to boost exports and help revive the economy, trade officials say.

U.S. exports of beef and pork are on track to hit $5 billion each for the first time, the U.S. Meat Export Federation estimates. Pork exports to China quadrupled from 2005 to 2010 to $463 million but are still only 2-3 percent of the market.

"China is a potentially huge market for us," said Dave Warner, spokesman for the National Pork Producers Council.

Part of a class of drugs called beta-agonists, ractopamine mimics stress hormones, making the heart beat faster and relaxing blood vessels. Some beta-agonists are used to treat people with asthma or heart failure, but ractopamine has not been proposed for human use.

In animals, ractopamine revs up production of lean meat, reducing fat. Pigs fed the drug in the last weeks of their life produce an average of 10 percent more meat, compared with animals on the same amount of feed that don't receive the drug. That raises profits by $2 per head, according to the drug's manufacturer, Elanco, a division of Eli Lilly. It sells the drug under the brand name Paylean.

Ractopamine leaves animals' bodies quickly, with pig studies showing about 85 percent excreted within a day. But low levels of residues can still be detected in animals more than a week after they've consumed the drug.

While the Department of Agriculture has found traces of ractopamine in American beef and pork, they have not exceeded levels the FDA has determined are safe.

But because countries like China and Taiwan have no safety threshold, traces of the drug have led to rejection of some U.S. meat shipments. The EU requires U.S. exporters to certify their meat is ractopamine-free, and China requires a similar assurance for pork.

Some U.S. food companies also avoid meat produced with the feed additive, including Chipotle restaurants, meat producer Niman Ranch and Whole Foods Markets.

The FDA ruled that ractopamine was safe and approved it for pigs in 1999, for cattle in 2003 and turkeys in 2008. As with many drugs, the approval process relied on safety studies conducted by the drug-maker — studies that lie at the heart of the current trade dispute.

Elanco mainly tested animals — mice, rats, monkeys and dogs — to judge how much ractopamine could be safely consumed. Only one human study was used in the safety assessment by Elanco, and among the six healthy young men who participated, one was removed because his heart began racing and pounding abnormally, according to a detailed evaluation of the study by European food safety officials.

Testing for drug residues in meat is limited in U.S.

The U.S. Department of Agriculture's Food Safety and Inspection Service, responsible for the safety of the meat, poultry, and processed egg supply, runs a National Residue Program to ensure that widely-used veterinary drugs, like growth-promoters and antibiotics, do not end up in the nation's food supply.

Though ractopamine is widely used in pigs and cattle, testing for ractopamine residues in food animals is limited.

Last year, for example, no tests were conducted on 22 billion pounds of pork produced in the United States; 712 samples were taken from 26 billion pounds of beef but the results have not yet been released.

Between 2007 and 2009, the testing program detected ractopamine in a total of 20 pork and 7 beef samples — all below the safe residue limits set by the U.S. Food and Drug Administration, the agency charged with overseeing veterinary drugs.

Though the drug has been approved for use in turkeys since 2008, to date there has been no government testing for ractopamine residues.

Some scientists have raised issue with the general lack of research into the impact of veterinary drugs on human health.

"There's very little data on the low levels of veterinary drugs people are exposed to," said Keeve Nachman, a scientist who directs the Farming for the Future program at the Johns Hopkins School of Public Health in Baltimore. "We don't know much about the toxicological significance of these exposures, and no one is really looking."

With tightening budgets—and a new focus on additional strains of E. coli as well as stricter poultry standards—food safety resources at USDA have been shifted away from testing chemical and drug residues, according to FSIS officials.

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"The reality is that resources are scarce," said one FSIS official. "We are sometimes asked to reduce the number of samples that we take."

— Helena Bottemiller

When Elanco studied the drug in pigs for its effectiveness, it reported that "no adverse effects were observed for any treatments." But within a few years of Paylean's approval, the company received hundreds of reports of sickened pigs from farmers and veterinarians, according to records from the FDA's Center for Veterinary Medicine.

USDA meat inspectors also reported an increase in the number of "downer pigs" — lame animals unable to walk — in slaughter plants. As a result of the high number of adverse reactions, the FDA requested Elanco add a warning label to the drug, and it did so in 2002.

The company also received a warning letter from the FDA that year for failing to disclose all data about the safety and effectiveness of the drug.

Since the drug was introduced, more than 160,000 pigs taking ractopamine were reported to have suffered adverse effects, as of March 2011, according to a review of FDA records. The drug has triggered more adverse reports in pigs than any other animal drug on the market. Pigs suffered from hyperactivity, trembling, broken limbs, inability to walk and death, according to FDA reports released under a Freedom of Information Act request. The FDA, however, says such data do not establish that the drug caused these effects.

"I've personally seen people overuse the drug in hogs and cattle," said Temple Grandin, a professor at Colorado State University and animal welfare expert. "I was in a plant once where they used too much ractopamine and the pigs were so weak they couldn't walk. They had five or six people just dedicated to handling the lame pigs."

But she noted that producers have since scaled back use in response to the rash of illnesses.

"Our company takes adverse event reporting very seriously and is overly inclusive on the information we submit to ensure we're meeting all requirements," Elanco spokeswoman Colleen Par Dekker said. She said the label change in 2002 resulted from an ongoing process of evaluating adverse effects of the drug, adding that an industry trend towards heavier pigs contributed to rising numbers of lame animals in

towards heavier pigs contributed to rising numbers of lame animals in this period.

By 2003, with ractopamine rolling out across the livestock industry, U.S. trade officials began pressing to open world markets for meat produced with the feed additive. Their effort focused on a relatively obscure corner of the trade world — the U.N.'s Codex Alimentarius Commission, which sets global food-safety standards.

Setting a Codex standard for ractopamine would strengthen Washington's ability to challenge other countries' meat import bans at the World Trade Organization.

The issue has reached the last step in Codex's approval process, but since 2008 the commission has been deadlocked over one central question: What, if any, level of ractopamine is safe in meat?

Held up at Codex. Read our exclusive coverage here.

The EU and China, which together produce and consume about 70 percent of the world's pork, have blocked the repeated efforts of U.S. trade officials to get a residue limit. European scientists sharply questioned the science backing the drug's safety, and Chinese officials were concerned about higher residues in organ meats, which are consumed in China.

"The main problem for us is that the safety of the product could not be supported with the data," said Claudia Roncancio-Peña, a scientist who led the European food safety panel studying the drug.

U.S. trade officials say China wants to limit competition from U.S. companies, and the EU does not want to risk a public outcry by importing meat raised with growth-promoting drugs, which are illegal there.

The issue also has strained the U.S.-Taiwan trade relationship, since Taiwan -— the sixth-largest market for U.S. beef and pork —- began testing for ractopamine last year. It found traces in American beef and pork and pulled meat from store shelves, according to local press reports.

In the U.S., residue tests for ractopamine are limited. In 2010, for

example, the U.S. did no tests on 22 billion pounds of pork; 712 samples were taken from 26 billion pounds of beef. Those results have not yet been released.

Updated on March 23: *The FDA on March 14 issued a statement in response to this report, saying it had reviewed its previously published adverse drug effect numbers on ractopamine. After excluding reports of ineffectiveness, meat abnormalities and fertility abnormalities, it said the number of animals with reports of adverse effects was 160,917. The story reflects this recent analysis by the FDA.*

Updated on Feb. 22: *A clarification to the Jan. 25, 2012, story "Dispute over Drug in Feed, Limiting US Exports" has been issued, making clear that the adverse drug effects for ractopamine were reported to the FDA. The story adds that the FDA says such data do not establish that the drug caused these effects.*

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